



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

AT

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,449	07/13/2001	Avi Ashkenazi	10466/58	1667
9157	7590	06/29/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			MOSHER, MARY	
		ART UNIT		PAPER NUMBER
		1648		

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/905,449	ASHKENAZI ET AL.
	Examiner	Art Unit
	Mary E. Mosher, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 44-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 44-46 and 49-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

Claims 44-46 and 49-51 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al 5,942,606.

The sole issue remaining in this application is whether or not Lal et al is available as prior art, and this issue turns upon whether or not the invention as claimed is enabled by the disclosure in provisional application 60/062,816, filed prior to Lal. The examiner has denied benefit on the grounds that 60/062,816 does not meet the how-to-use requirement of 35 USC 112, first paragraph, because prior to the disclosure of VEGF-inhibitory activity none of the asserted uses could be practiced without undue experimentation.

Applicant maintains that, in the provisional application, the disclosure of structural similarity between the claimed polypeptide and the CAR virus receptor was sufficient to teach one skilled in the art how to use the claimed polypeptide as a novel cell surface virus receptor. The examiner has cited art as evidence that similarity in structure does not equate to similarity in function for a virus receptor. The examiner also pointed out in the office action mailed 10/2/2002 that there was no information regarding what viruses, if any, use the claimed polypeptide as a receptor. Applicant points to the similarity in disclosure between the provisional application and the Lal specification, and argues (1) if the Lal disclosure is presumptively enabling then the provisional disclosure should also be considered enabled, and (2) if the provisional disclosure is not enabling then neither is the Lal disclosure, and enablement is required for anticipation.

Regarding argument (1), each application is treated on its own merits. In this application, the examiner has provided reasons to reach a prima facie conclusion that, in the provisional application, the disclosure did not meet the how-to-use requirement of 35 USC 112, first paragraph, and applicant has not provided convincing arguments or evidence to overcome that prima facie conclusion.

Regarding argument (2), Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research, 68 USPQ2d 1373, 1376 (CA FC 2003) does quote Bristol-Myers Squibb v. Ben Venue Laboratories, Inc., 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001), stating “To anticipate the reference must also enable one of skill in the art to make and use the claimed invention.” However, this passage in Bristol-Meyers appears only in the context of a citation to In re Donohue, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985); Donohue in turn deals exclusively with issues of making the asserted prior art compound. Elan itself also deals with issues whether the asserted prior art teaches how to make the product in question. The cited page of Amgen, Inc. v. Hoechst Marion Roussel, Inc. 65 USPQ2d 1385, 1416 (Fed Cir 2003) states: “Long ago our predecessor court recognized that a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if that disclosure fails to ‘enable one of skill in the art to reduce the disclosed invention to practice.’ [citations omitted].” Therefore, the statement that an anticipating reference must teach how to “use the claimed invention” appears to be dicta, not a reversal of In re Schoenwald (22 USPQ2d 1671, Fed Cir 1992).

Art Unit: 1648

To quote Robert L. Harmon in the reference book Patents and the Federal Circuit, Fifth Edition, (BNA Books, Washington DC, 2001, page 85): "If compositions are known, for any use or no use, they are not patentable as compositions, by force of §102... It is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." Lal teaches how to make the protein that applicants are claiming, and Lal conveys possession of the protein by disclosing its full structure. Therefore, the disclosure in Lal is sufficient for anticipation, regardless of what Lal may teach or fail to teach about how to use the protein.

Applicant's arguments are unconvincing, and the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/24/04

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600